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By: /s/ Serene Keen

Date: May 17, 2010

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES**

Appl. No.	:	10/010,246	Confirmation No.:	5866
Appellants	:	Robert Sixto, Jr., et al.		
Filed	:	12/06/2001		
TC/A.U.	:	3773		
Examiner	:	Darwin P. Erez		
Docket No.	:	SYN-064C		
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MAIL STOP: APPEAL BRIEF - PATENTS

Commissioner for Patents

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REPLY BRIEF

Sir:

The following Reply Brief is being submitted in response to the Examiner's Answer issued on March 19, 2010, which was in response to Appellants' Amended Appeal Brief filed on December 10, 2009.

REPLY

In Appellants' December 10, 2009 Amended Appeal Brief, a portion of Appellants' argument addressed the Examiner's rejection of claims 1, 2, 4, 17, 18, 21-23, 25, and 32 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,620,452 to Yoon (hereinafter "*Yoon*"). Appellants argued that the rejection is improper for at least the reason that the Examiner has failed to establish that the *Yoon* reference describes a surgical clip having a bridge that connects a first arm and a second arm to form a substantially static U-shaped structure and, particularly fails to show a U-shaped structure that is retained prior to, throughout and subsequent to application of the clip, each of which is a required element of each independent claim of the present application (i.e. claims 1, 17, 21, 22, and 32). A rejection under 35 U.S.C. §102(b) is proper "only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987) (emphasis added); MPEP §2131.

As set forth in detail in Appellants' Amended Appeal Brief, the present invention concerns a surgical clip inserted by a clip applier after the clip applier jaws grasp and puncture an invaginated tissue fundus. *See e.g.*, pp. 19-21 of the application as originally filed. The surgical clip includes "two arms 312, 314 connected by a

bridge 316. Both arms terminate in retainers 320, 322, each having a sharp end 321, 323.” *Id.*, at p. 25, lines 5-8. During application, the tissue is plicated and the retainer arms are caused to slide over the tissue for a distance. *Id.*, at pp. 19-21. Then, only the retainer portion of the surgical clip is plastically deformed to affix the clip to the fundus. *Id.*, at Fig. 13; element 22 in Figs. 17 and 18; elements 320 and 322 in Figs. 19 and 20. Unlike the retainer portion of the surgical clip, a property of the connecting bridge (316) is that its stiffness retains the two parallel arms (312, 314) in a “static” U-shaped form prior to, throughout, and subsequent to application. *Id.*, at p. 23 and Figs. 17-20. It is only the retainer portions 320 and 322 of the clip that deform (compare Fig. 19 to Fig. 20). Before, during, and after the bending process, the two arms 312 and 314 and the bridge 316 coupling the arms to each other maintain a static U-shape. *Id.* Because the shape of the surgical clip is “static,” the bridge does not just retain a U-shaped structure prior to, throughout, and subsequent to application; it retains substantially the same initial U-shaped structure prior to, throughout, and subsequent to application such that the shape and diameter of the U-shape does not change at any time in any relevant way. The static nature of the bridge provides the structural ability for the arms to remain stiff and fixed in the static U-shape in a supportive position while allowing the retainer to deform.

Also set forth in detail in Appellants' Amended Appeal Brief, the embodiment of the clip shown in Fig. 10 of *Yoon*, which forms the basis for the Examiner's argument, is not shown or described as maintaining a "static" U-shaped configuration as that term has been defined by Appellants. Appellants do not deny that *Yoon's* FIG. 10 does show a U-shaped structure. However, the U-shape is only present prior to application of the clip. As Figs. 1-5 and 12-15 of *Yoon* show, the clip is designed to be compressed flat and the shape of *Yoon's* clip completely changes and becomes deformed as it is applied to the tissue (T). Therefore, the clip in *Yoon* does not have a "substantially static U-shaped structure retaining the shape prior to, throughout, and subsequent to application," as is recited by independent claims 1, 17, 21, 22, and 32 of the present application.

Despite this clear difference between the clip structures of *Yoon* and the claimed invention, the Examiner has maintained the argument that the "clip of *Yoon* is also fully capable of retaining its substantially U-shaped configuration prior to, throughout, and subsequent to application (the amount of separation between the two arms merely depends on the amount of force used to press the arms together)." See e.g., *Examiner's Answer*, pp. 3-4 and 6-7. In advancing this argument, the Examiner specifically points to Figs. 10, 12, and 15 of *Yoon* as showing the clip having a bridge that maintains a U-shaped configuration in an undeployed state, a

deployed state, and an “in-between state” if even pressure is applied to the clip arms during application. *Id.*, at p. 6. However, the Examiner’s argument is completely indifferent to the term “static” as it is used by Appellants in claims 1, 17, 21, 22, and 32. Thus, it is this particular argument that Appellants wish to address in this Reply Brief.

Respectfully, Appellants submit that the Examiner is imposing a construction of the term “static” that is inconsistent with Appellants and, where Appellants are afforded the right to act as their own lexicographers, is also improper. According to the Examiner, the limitation of “a static U-shaped structure” does not impose any structural size or dimension, but merely describes the shape of the structure.” *Id.* Although the Examiner disagrees with Appellants’ definition of the term “static” and wishes to broadly interpret “static” to only mean that the bridge maintains a changing U-shape, and not to mean that the bridge statically maintains the same, unchanging U-shape that it initially was in prior to application of the clip, Appellants do not believe that is the proper role of the Examiner, particularly where Appellants’ definition is clearly supported in the present application. MPEP §2173.05(a).

In addition, Appellants respectfully disagree with the Examiner’s argument that the clip in *Yoon* is “fully capable” of retaining its substantially U-shaped configuration

prior to, throughout, and subsequent to application and that it is just a matter of applying a steady or even amount of pressure to the clip arms. As depicted in Figs. 13-15, it is impossible for the base 14 of the clip to maintain the same U-shape throughout application of the clip if the staple legs 50 are to successfully occlude the tissue. To first position the tissue (T) between arms 16 and 18 of the clip, the staple legs 50 must be retracted into the arms as shown in Fig. 12, and therefore, the arms and the base of the clip must initially have a wide, open configuration. *See Yoon*, col. 5, lines 27-32. To then penetrate the tissue (T), the clip must be compressed in order to cause the tissue penetrating legs 50 to be driven through openings in the arms and into the tissue as shown in Fig. 13. *Id.*, at col. 5, lines 32-35. To compress the clip, the arc of the base of the clip must bend to become smaller, particularly if the Examiner is correct in the assumption that the arms can end up parallel to one another at the end of the application process. Finally, to lock the arms together to retain the clip in place, the clip must be compressed to the point where the arms 16 and 18 are separated by a distance somewhat less than the length of the tissue penetrating legs 50 such that the legs 50 pass through apertures 36 in the opposing arm and are bent around the other side as illustrated in Fig. 15. *Id.*, at col. 5, lines 35-47. Therefore, the arc of the base of the clip must bend to such a degree to ensure that the staple legs 50 come through the apertures of the bottom arm and can be bent to secure them in place. Accordingly, it cannot be said

that the U-shape of the base or bridge of the clip in *Yoon* can remain static and still allow the clip to function as intended. Furthermore, Appellants believe it is not reasonable to suggest that an even amount of pressure can be applied to the two arms of the clip, such that they remain parallel to one another throughout the application process, and still provide enough leverage to bend the arc of the base 14 so that the clip can be successfully applied to the tissue. Thus, Figs. 3 and 14 of *Yoon*, which show the intermediate state of the clip being applied to the tissue, depict the arms being tapered towards one another in order to provide enough force to bend the arc of the base 14. Appellants respectfully disagree with the Examiner's discounting of this distinction as being a difference in the methodology of applying the clip and not a difference in the structure of the clip. See *Examiner's Answer*, p. 7. This difference is due to the fact that the clip in *Yoon* is not retained in place after being applied to the tissue in the same structural manner as the claimed invention, i.e. by at least one deformable retainer extending from the end of at least one of the arms. Rather, it is being retained in place by a mating hook (e.g. element 23 in Fig. 3) or the staple legs 50 which requires the entire clip, arms and all, to be compressed together.

In conclusion, Appellants have shown that *Yoon* cannot be said to anticipate the present invention under 35 U.S.C. §102(b) because *Yoon* does not teach or disclose

each and every element of each rejection claim (i.e. claims 1, 17, 21, 22, and 32). The Examiner has misconstrued the surgical clip in *Yoon* as being capable of having a bridge that connects a first arm and a second arm to form a substantially **static** U-shaped structure and, particularly fails to show a **U-shaped structure that is retained prior to, throughout and subsequent to** application of the clip. It is therefore respectfully submitted that the rejection under 35 U.S.C. §102(b) has been overcome and should be reversed by the Board. For the foregoing reasons, allowance of claims 1-10, 17-18, and 21-32, as now presented, is believed to be in order. It is respectfully requested that this Board reverse the final rejection by the Examiner in all respects.

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Respectfully submitted,

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